

Public Chapter 277

SENATE BILL NO. 834

**By Cooper, McNally, Cohen, Rochelle, Crutchfield, Williams, Davis, Springer,
Dixon, Haun**

Substituted for: House Bill No. 772

By Jackson, Caldwell, John DeBerry, Ulysses Jones, Armstrong, West, Tidwell, Phelan,
Givens, McDonald, McMillan, Ralph Cole, Langster, Williams, Hood, Eckles, Davidson,
Odom, Rhinehart, Sherry Jones, Winningham, Ronnie Cole, Roach, Rinks, McKee, Lois
Deberry, Ridgeway, Maddox, Whitson, Patton, Ford, Cross, Miller, Cooper, Sargent,
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Mumpower, Bird, Pinion, Davis, Huskey, Sands, Towns, Brooks, Fitzhugh, Boner, Kerr,
Robinson, Pruitt, Haley,
Mr. Speaker Naifeh

AN ACT To amend Tennessee Code Annotated, Title 56, relative to insurance coverage
for drugs including life-threatening illnesses, such as cancer, AIDS, and coronary
heart disease.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, Part 23, is
amended by adding the following as a new section:

Section___. (a) The legislature finds and declares the following:

(1) The citizens of this state rely upon health insurance to cover
the cost of obtaining health care.

(2) It is essential that the citizens' expectation that their health
care costs will be paid by their insurance policies is not disappointed and
that they obtain the coverage necessary and appropriate for their care
within the terms of their insurance policies.

(3) Some insurers deny payment for drugs that have been
approved by the federal Food and Drug Administration (FDA) when the
drugs are used for indications other than those stated in the labeling
approved by the FDA (off-label use) while other insurers with similar
coverage terms do pay for off-label use.

(4) Denial of payment for off-label use can interrupt or effectively
deny access to necessary and appropriate treatment for a person being
treated for a life-threatening illness.

(5) Equity among employers who obtain insurance coverage for their employees and fair competition among insurance companies requires that insurance companies assure citizens reimbursement for drugs in the same way and in the way citizens expect.

(6) Off-label use of an FDA-approved drug is legal when prescribed in a medically appropriate way and is often necessary to provide needed care. Approximately fifty percent (50%) of cancer drug treatment is for off-label indications. The FDA and the federal Department of Health and Human Services recognize the wide variety of effective uses of FDA-approved drugs for off-label indications. Information on the appropriate off-label use of FDA-approved drugs is obtained from compendia published by the United States Pharmacopeial Convention, the American Medical Association, and the American Society of Hospital Pharmacists. In addition, scientific studies of off-label use of drugs published in recognized peer-reviewed professional journals provide information on appropriate use of drugs for off-label indications. The Omnibus Budget Reconciliation Act of 1990 recognizes these three (3) compendia and peer-reviewed literature as appropriate sources for reimbursement and requires Medicaid agencies to pay for off-label use of drugs prescribed for Medicaid patients if the use is stated in any of such sources. The Omnibus Budget Reconciliation Act of 1993 applies the same criteria and coverage to Medicare patients. Twenty (20) states have also passed similar legislation, most based on uniform legislation. The National Association of Insurance Commissioners has also adopted a model act based on the ACCC model legislation.

(7) Use of FDA-approved drugs for off-label indications provides efficacious drugs at a lower cost. To require that all appropriate uses of a drug undergo approval by the FDA would substantially increase the cost of drugs, delay or even deny patients' ability to obtain medically effective treatment. FDA approval for each use would require substantial expenditure and time to undergo the clinical trials necessary to obtain FDA approval. This is particularly the case when a drug is off-patent and in generic production, and consequently is available at a lower price. Once a drug is in generic production by multiple manufacturers, it is not economically feasible for a manufacturer to incur the cost of FDA approval.

(8) Reimbursement for off-label indications of FDA-approved drugs is necessary to conform to the way in which appropriate medical treatment is provided, to make needed drugs available to patients, and to contain health care costs.

(9) The provisions of this section shall not apply to a governmentally funded health care program, if such program requires the provision of medically necessary services.

(b) For the purposes of this section, unless the context requires otherwise:

(1) "Insurance policy" means any individual, group, or blanket policy written by a medical expense indemnity corporation, a hospital service corporation, a health care service plan contract, or a private insurance plan issued, amended, delivered or renewed in this state, or which provides such insurance for residents of this state.

(2) "Standard reference compendia" means (A) the United States Pharmacopoeia Drug Information; (B) the American Medical Association Drug Evaluations; or (C) the American Hospital Formulary Service Drug Information.

(3) "Medical literature" means published scientific studies published in any peer-reviewed national professional journal.

(c)(1) No insurance policy or contract regulated under this title which provides coverage for drugs shall exclude coverage of any such drug for a particular indication on the ground that the drug has not been approved by the federal Food and Drug Administration for that indication, if such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature. Provided, however, nothing in this section shall be construed to authorize the Commissioner of Health to approve any such drug or direct any person which issues an insurance policy to make payments for such drug for a particular indication unless such drug is recognized for treatment of such indication in one of the standard reference compendia or in the medical literature.

(2) Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.

(3) This section shall not be construed to alter existing law with regard to provisions limiting the coverage of drugs that have not been approved by the federal Food and Drug Administration.

(4) This section shall not be construed to require coverage for any drug when the federal Food and Drug Administration has determined its use to be contra-indicated.

(5) This section shall not be construed to require coverage for experimental drugs not otherwise approved for any indication by the federal Food and Drug Administration.

(6) Any dispute about coverage for off-label uses brought to the Commissioner of Health shall be resolved by the appropriate court-approved grievance process authorized by the department.

(7) The Commissioner of Health shall have the authority to direct any person who issues an insurance policy to make payments required by this section.

SECTION 2. This act shall take effect July 1, 1997, the public welfare requiring it, and it shall apply to contracts entered into or renewed on or after July 1, 1997.